UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

UNITED STATES and STATE OF TEXAS ex rel. DANIEL W. ELLIOTT, M.D. et al.,	§	
v.	§	Case No. 2:20-cv-00132-JRG
SOUTHEAST TEXAS MEDICAL ASSOCIATES, LLP; et al.	§	

DEFENDANT ONPOINT LAB, LLC'S REPLY IN SUPPORT OF MOTION TO DISMISS COMPLAINT

In response to the Complaint (Doc. 2), Defendant OnPoint Lab, LLC ("OnPoint") moved to dismiss (Doc. 63) and Relators responded (Doc. 89). OnPoint replies, respectfully stating:

The Complaint does not meet the heightened pleading requirements of Rule 9(b) and the plausibility requirements of Rule 8(a) because Relators rely upon facts that are equally consistent with a lab that maintains specialized equipment for handling more complex drug tests, such that essential elements of each claim are absent. Relators do not know which lab processed blood tests for SETMA Medicare patients that were coupled with transportation charges. Relators do not know the source of the complex urine tests that resulted in OnPoint's Medicare claims. Relators therefore fail to plausibly allege a brazen multi-million dollar conspiracy to ignore the law.

I. The Facts Are Consistent with Legal and Obvious Alternative Explanations.

All of the claims fail to meet the applicable pleading standards because, as controlling law provides, "A claim is merely conceivable and not plausible if the facts pleaded are consistent with both the claimed misconduct and a legal and 'obvious alternative explanation.'" *See United States ex rel. Integra Med Analytics, L.L.C. v. Baylor Scott & White Health*, 816 F. App'x 892, 897 (5th

Cir. 2020). In other words, if a relator merely sees a person go into a bank and come back out with money in hand, that relator cannot plausibly allege a bank robbery occurred, since there are two conceivable scenarios: the person robbed the bank or the person made a withdrawal from the bank. A complaint that does not relate what happened in the bank does not meet the pleading standard.

In the *Integra Med* case, the relators similarly produced statistics and concluded the worst from those statistics. The statistics indicated Baylor's physicians were adding secondary diagnoses at a rate that doubled comparable hospitals, which produced higher revenues for Baylor and its physicians. *Id.* at 894-95. But, the statistics were "consistent with both Baylor having submitted fraudulent Medicare reimbursement claims to the government and with Baylor being ahead of most healthcare providers in following new guidelines from CMS." *Id.* at 897. The Fifth Circuit held that statistical data does not meet the pleading standards of Rule 8(a) and 9(b) as applied in a false claims case where the statistics are "also consistent with a legal and obvious alternative explanation." *Id.* at 898.

In this case, Relators seek to demonstrate misconduct as to two sets of claims. They first seek to interpret the reason for the existence of a body of claims submitted by SETMA for intravenous blood draws from Medicare patients for which transportation charges were submitted on the basis they were remotely collected from homebound or nursing home patients (Doc. 2 at 40-50, ¶¶141-167). In asserting these blood draws were sent to OnPoint, Relators place great weight on statistics reflecting SETMA blood draw claims had a high number of corresponding transportation charges (Doc. 2 at 44-45, ¶¶154ff – "Once the blood had been taken from the patients' veins, Defendants could send it to Sugar Land for testing. But first, they had to get it there. One of the Level II HCPCS codes is P9603. This code is intended to apply only for '[t]ravel allowance . . . ."). But, in truth, Relators have no idea where the blood was being drawn, nor to where it was being transported. It is equally conceivable that SETMA doctors actually had nursing

home patients scattered in a 50 mile radius around Beaumont. The samples could have been legally transported to an onsite SETMA lab in Beaumont. *See* 42 C.F.R. §411.355(b) (permitting in-office ancillary services). OnPoint posited this alternative explanation in its motion (Doc. 63 at 3). In their response, Relators simply ignore this explanation.

As to the second set of claims, Relators next seek to discern why OnPoint principally submitted claims for complex urine tests (Doc. 2 at 52-53). But, the explanation is in the Complaint: OnPoint developed and advertised a capacity to process complex urine samples that required specialized equipment and personnel (*id.* at 36, ¶ 126). Notably, the Complaint does not allege these urine samples were transported at all (*see id.* at 50-54). So, by Relators' own reasoning, one should conclude the referring physicians were located near OnPoint in Houston. Secondarily, Relators assert testing a patient more than once a year patently establishes a lack of medical necessity because it would be inconsistent with the patient population they observed at SETMA. But yet, the Complaint observes that there are practices that focus on patients with a history of substance abuse (*id.* at 38, ¶131). This again indicates the OnPoint claims derived from the practices of other physicians. Here too, OnPoint pointed out this legitimate alternative scenario in its motion (Doc. 63 at 3). And, Relators say nothing directly in response.

Relators rely heavily upon the notion that the mere existence of SETMA physician investments in OnPoint means there were self-referrals that produced false Medicare claims. But, Relators wholly overlook the fact SETMA physicians could have justified their investments by only referring privately insured patient samples to OnPoint, and by investing in a specialty lab in the Houston market. Neither of these two explanations involves a brazen conspiracy to break laws that have been only the books for many years and that have been widely enforced. It is therefore equally conceivable that Relators observed conduct that produced revenues not derived from the government.

Turning to the facts to which Relators point in their Response, one can see, with the foregoing in mind, that the facts fit equally with the two legitimate explanations stated above. The facts Relators cite are:

(1) Mr. Bryant monitored the number of SETMA drug tests (Doc. 84 at 2);

(2) Mr. Bryant said referring to a lab owned by SETMA physicians could be legal (*id.*);

(3) Dr. Castro sent an email that said "Come on guys . . . we need to order more drug screens" (*id.*);

(4) The drug screens were complex and required a specialized lab (*id.* at 3);

(5) OnPoint is a specialized lab that opened in 2014 (*id.*);

(6) The individual physicians own interests in OnPoint (*id.*);

(7) The physicians began ordering more complex blood draws in 2014 (*id.* at 3-6);

(8) OnPoint submitted claims primarily for complex tests (*id.* at 6);

(9) OnPoint submissions average 1.9 tests per patient per year (*id.* at 7);

(10) SETMA physician claims include many with transportation costs (*id.*);

(11) The transportation costs pertain to homebound or nursing home draws (*id.* at 8);

(12) The number of transported draw claims is high relative to other practices (*id.* at 8-11);

(13) After they left SETMA, Drs. Dao and Arcala ceased billing transportation (*id.* at 11).

Taking each fact in turn, one can see this second scenario fits entirely with these facts:

(1) Mr. Bryant's monitoring of drug tests in the aggregate provides no specific insight;

(2) Mr. Bryant's comment that it is legal to refer patients to partially owned labs without creating false Medicare claims is true and disclosure of the financial relationship in the form of a sign in the lobby is required if (a) private or commercial pay referrals of urine samples were being sent to OnPoint and Medicare samples were being further referred to unaffiliated labs, or (b) a lab owned by physicians of SETMA, or a wholly owned

subsidiary lab of SETMA, fits within the exception at 42 C.F.R. §411.355(b), also referred to as the In-office Ancillary Services exception;

(3) Dr. Castro's efforts to encourage drug screens could ensure proper monitoring of any patient being prescribed opioids for pain management;

(4) The fact complex drug screens require a specialized lab is actually an explanation for the high concentration of such tests by a lab like OnPoint;

(5) OnPoint may have entered the market for specialized complex urine sample testing because there was a market need in and around Houston as well as an opportunity to process private pay urine samples sent by SETMA physicians;

(6) Physicians who set up a lab for the purpose of handling private pay urine samples do not thereby create false Medicare claims;

(7) The SETMA physicians may have developed or expanded relationships with nursing homes and invested in OnPoint's facilities in the same year;

(8) OnPoint naturally submitted Medicare claims primarily for complex urine tests because that is its specialty, and those claims could have come from other physician practices entirely;

(9) OnPoint submissions average 1.9 tests per patient per year because that was what the physicians who ordered the tests believed to be medically necessary for patients about whom Relators have no knowledge at all, since OnPoint's Medicare business came from Houston area physicians;

(10) SETMA physicians may have had transportation costs associated with remote collections of blood draws from nursing home patients scattered over a 50 mile radius around Beaumont that were not sent to OnPoint at all, such that SETMA submitted

claims with a high volume of transportation charges relative to Texas physicians who do not have as many nursing home arrangements;

(11) The fact the transportation costs pertain to the code for homebound or nursing home draws is consistent with a SETMA remote nursing home practice;

(12) The number of transported blood draw claims is high relative to other practices because other physicians do not have as many nursing home patients; and

(13) After they left SETMA, Drs. Dao and Arcala ceased billing transportation because they were no longer handling patients at the nursing homes with whom SETMA had a relationship.

II. The Existence of Equally Conceivable Explanations Defeats All of Relators' Claims.

The inability to provide facts establishing illegal conduct, as opposed to merely conceiving of the possibility of such conduct, is fatal to Relators' effort to allege essential elements of each of their claims.

A. Relators fail to sufficiently allege scienter.

All claims fail for want of facts establishing scienter. Relators acknowledge they must sufficiently allege OnPoint acted with the requisite scienter, and they take no issue with the above cited *Integra Med Analytics* case from the Fifth Circuit holding that the existence of an equally plausible alternative scenario dispels speculation of wrongdoing. Since there are such alternative scenarios here, the assertion OnPoint's state of mind was to brazenly conspire to submit $3 million in Medicare claims has an inadequate foundation. The truth is that Relators, lacking any involvement with OnPoint, cannot satisfy the applicable pleading standards in regard to OnPoint's state of mind. The facts they allege are equally in line with a state of mind at OnPoint to profit from private pay SETMA claims, and local Houston physician Medicare referrals based upon OnPoint's specialty. Neither of these lines of business would create false Medicare claims.

B. Relators fail to allege other essential elements of each FCA Claim.

For similar reasons, Relators have failed to meet their burden in regard to other essential elements. The following takes each claim in turn.

1) Relators fail to adequately plead a "presentment claim" under § 3729(a)(1)(A).

Relators do not point to a single claim with a specific understanding of the patient involved. As such, Relators' speculation is both implausible and lacks specificity. *Integra Med.,* 816 Fed. Appx. at 898 ("Insofar as Integra Med purports to give specific examples of fraudulent claims, it also fails to meet the pleading requirements of Rules 8(a) and 9(b). Integra Med's examples simply give some identifying patient information and pair it with a diagnosis. No example gives any indication about what makes it a false claim. The claims of falsity are simply conclusory.").

In their Response, Relators' inability to credibly answer the "what" question sensibly is particularly telling (Doc. 84 at 18). Here, Relators try to blur what claims are at issue by first referring to the supposedly medically unnecessary blood draws supposedly transported to OnPoint at the direction of SETMA physicians. But, Relators do not assert OnPoint presented those claims; rather, Relators then shift to point to the portions of the Complaint referring to the claims OnPoint submitted for complex urine tests (*id., citing* Doc. 2 at ¶¶168-79). As to those claims, Relators lack the "transportation" theory. As such, those tests could have been submitted by local Houston physicians. As the Complaint acknowledges, OnPoint developed and advertised a capacity to process complex urine samples that required specialized equipment and personnel (Doc. 2 at 36, ¶ 126). Also, as to frequency, the Complaint observes that there are practices that focus on patients with a history of substance abuse where testing per patient would be more frequent (*id.* at 38, ¶130) ("Depending on the particular patient's risk profile and medical history, such patients should be screened periodically throughout the year, with the norm for such patients generally being

approximately every three months. Periodic drug testing may also be appropriate for patients with a personal or family history that indicates an elevated risk of drug abuse."). The Complaint then contrasts such patients with the SETMA patients (*id*. at 38, ¶131). All of this points to principally Houston based patients that fit the statistics.

The statement as to "where" employs the same attempt to confuse the blood draws and the urine samples (Doc. 84 at 18-19). Here, Relators assert "the medical transport data supports a reasonable inference that SETMA samples were transported to and from OnPoint" (*id.*). But, the OnPoint claims described in the "what" section do not fit this "where" statement.

Notably absent from the Complaint, and the response, is a discussion of a single claim that fits with the illegal referral scheme Relators imagine. Inconsistent speculation from statistics and fragmentary knowledge does not meet the Rule 9(b) standard to plead wrongful claim presentment.

2) Relators fail to adequately plead a "false records claim" under § 3729(a)(1)(B).

Relators rely upon the same assertions in arguing that they have alleged a false records claim (Doc. 84 at 23 – "As explained above, …"). Thus, for the same reasons, Relators fail to satisfy the pleading standards for a false records claim.

3) Relators fail to allege sufficiently a conspiracy to violate the FCA.

Relators do not identify an agreement, but merely assert one must have existed (Doc. 84 at at 24). But, the facts alleged fit with a scenario in which none of the OnPoint Medicare claims came from SETMA referrals. One cannot infer an agreement to do wrong from inconclusive facts.

4) Relators fail to adequately plead a "reverse false claim" under § 3729(a)(1)(G).

Relators' brief confirms OnPoint's assertion that Relators have merely recast their earlier claims (Doc. 84 at at 25). This claim should therefore be dismissed for the same reasons.

C. Relators' state law allegations fail for the same reasons as the federal claims.

Relator's response brief confirms Relators make no attempt to distinguish the statutes relied upon from Claims Five through Seven from federal law and those claims should be dismissed for the same reasons as the federal claims (Doc. 84 at 26). The State of Texas has filed a brief indicating some points of law might be different, but Relators make no attempt to show that any such differences apply here.

D. Relators impermissibly rely on puzzle and shotgun pleading.

OnPoint's principal position is that the Complaint asserts two types of claims – the blood draws for which SETMA submitted claims with transportation charges based upon the assertion that they were remotely collected at a nursing home, and the urine tests for which OnPoint submitted claims based without charging for transportation. But, Relators attempt to blur the two together. When challenged about this, Relators assert they mean to refer in each cause of action to "any claims submitted by OnPoint, SETMA, or the Defendant Physicians" (Doc. 84 at 28). But, this is not proper. There are two classes of claims, each with their attendant facts. Applying Relators' approach, one is left with a nonsensical situation in which, in Count 1, OnPoint is being held responsible for claims it did not submit, and, in Count 3, OnPoint is conspiring with itself to submit its own claims. For OnPoint to properly challenge each of the causes of action, OnPoint is entitled to know what claims are specifically at issue, and what conduct goes along with each claim. This would prevent Relators from continuing to attempt to blur the two categories of Medicare claims and the facts relating to each of those categories of claims. Additionally, OnPoint's own conduct should be plainly delineated from that of the other Defendants, not lumped together. If the Court is able to separate the facts and rule upon the motion as presented, that is all well and good. But, if the Court finds the Complaint ambiguous, Relators should be required to replead.

WHEREFORE, OnPoint prays the Court dismiss Relators' Complaint.

Respectfully submitted,

Dennis Roossien
Dennis L. Roossien, Jr.
Tex. Bar No. 00784873
Munsch Hardt Kopf & Harr, P.C.
500 N. Akard, Ste. 3800
Dallas, Texas 75201
(214) 855-7535
droossien@munsch.com

ATTORNEY FOR ONPOINT LAB, LLC

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on all parties that have appeared through the Court's electronic filing system.

Dennis Roossien
Dennis L. Roossien, Jr.